

Appl. No. 10/087,142 (Docket 093/005)
Amdt. dated Nov. 15, 2005
Reply to Office Action of March 28, 2005

REMARKS/ARGUMENTS:

Applicants have canceled claims 1-12 and 14-20 without prejudice or disclaimer. Applicants reserve the right to reintroduce the subject matter of those claims at a later point in prosecution. Applicants have amended claim 13 and have added new claims 21-28, which all depend from claim 13. Claims 13 and 21-18 are now pending in this application. Reconsideration and allowance of the application is respectfully requested.

Double Patenting

Claims 1-4, 6, 7, 9, 10, and 13 are provisionally rejected over pending U.S. Application Serial No. 10/001,267 under the judicially created obviousness-type double patenting doctrine. Action at page 2. Claims 1-4, 6, 7, 9, and 10 have been canceled; therefore, the rejection of those claims is now moot. With regards to pending claim 13 (and claims 21-28), Applicants note that the double patenting rejection is still only provisional at this point. Applicants request abeyance of the rejection until issuance of the '267 application.

Rejection under 35 U.S.C. §101 of claims 1 and 3-20

The Office rejected claims 1 and 3-20 under 35 U.S.C. §101 of as allegedly not being supported by either a substantial or specific asserted utility or a well established utility. Action at page 4. The Office argued that the claimed systems for obtaining hepatocyte lineage cells and the methods for making such systems lack a "substantial or specific utility." *Id.* at page 5.

Applicants respectfully traverse the rejection and disagree with the Office's view that the claimed systems and methods for making such systems fail to have a utility. For example, the claimed systems can be used in the production of human ES cell-derived hepatocyte lineage cells (*see, e.g.*, page 6, lines 19-20 of specification). However, without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application, Applicants have canceled claims 1-12 and 14-20 without prejudice or disclaimer. Thus, the rejections of those claims are now moot.

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Pending claim 13 has been amended and now recites a method for obtaining hepatocyte lineage cells. As the Office noted, the "specification provides a clear utility for each of the separate cell populations," which separate cell populations include a population of hepatocyte lineage cells. Action at page 5. Thus, Applicants request reconsideration and withdrawal of the utility rejection of claim 13. New claims 21-28 depend from claim 13 and also recite methods for obtaining hepatocyte lineage cells.

Rejection under 35 U.S.C. §112, first paragraph of claims 1 and 3-20

The Office rejected claims 1 and 3-20 as allegedly lacking enablement under 35 U.S.C. §112, first paragraph. Action at page 6. The Office contended that "since the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention." *Id.* Thus, this rejection is essentially based on the utility rejection discussed above.

Applicants respectfully traverse the rejection and note the cancellation of claims 1-12 and 14-20 and the amendment to claim 13. Applicants assert the same arguments with regard to amended claim 13 and its dependents as asserted against the utility rejection. Applicants also note the Office's statement that the "specification provides specific uses for each of the cell populations" Action at page 7. Applicants therefore request reconsideration and withdrawal of this rejection.

Rejections under 35 U.S.C. §102(b) of claim 2 by Chen, Hoshi, and/or Kono

The Office rejected claim 2 as allegedly being anticipated under 35 U.S.C. §102(b) by Chen et al., Hoshi et al., and/or Kono et al. Action at pages 9 and 10. Applicants respectfully traverse the rejections. However, as noted above, Applicants have canceled claim 2 without prejudice or disclaimer, rendering these rejections moot.

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Fees Due

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, Applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

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LAST PAGE

USSN 10/087,142

Attorney Docket 093/005P